1

NON-INVASIVE METHOD AND SYSTEM FOR CHARACTERIZING CARDIOVASCULAR SYSTEMS FOR ALL-CAUSE MORTALITY AND SUDDEN CARDIAC DEATH RISK

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Provisional Patent Application No. 61/684,282, filed on Aug. 17, 2012, entitled 10 "NON-INVASIVE METHOD AND SYSTEM FOR CHARACTERIZING CARDIOVASCULAR SYSTEMS FOR ALL-CAUSE MORTALITY AND SUDDEN CARDIAC DEATH RISK," which is incorporated herein by reference in its entirety.

BACKGROUND

Present methods employed to assess cardiac and other physiological signals are typically rudimentary. It is claimed 20 that prior methods can be improved upon via techniques that identify novel ECG patterns using advanced mathematical techniques that assess dynamic alterations in cardiac conduction and repolarization along with alterations in vascular and autonomic function. The surface ECG contains information 25 on the electrical properties of the heart and represents the sum of electrical activity of the heart, along with vascular and autonomic nervous system dynamics. Moreover, cardiac electrical activity directly relates to cardiac architecture and alterations in cardiac architecture are detectable on a surface 30 ECG. The challenges are to winnow out information related to abnormalities in cardiac conduction and repolarization, cardiac architecture, along with vascular and autonomic function from noise and other artifacts and to identify novel ECG patterns that reliably predict the development of serious heart 35 rhythm disturbances, sudden cardiac death, other modes of death and all-cause mortality.

Prior ECG-based methods to identify patients at risk of sudden death and mortality are not sufficiently accurate. Even the best techniques have areas under the receiver operating 40 characteristic curve of 0.80 or less in predicting the development of serious heart rhythm disturbances, sudden cardiac death, and mortality. Hence at least 20% of patients are misclassified. A more accurate method to characterize abnormalities in cardiac conduction and repolarization, cardiac 45 architecture, along with vascular and autonomic function is desirable and necessary. Essential to the clinical utility of this method is the identification of novel ECG patterns that are closely linked to the subsequent development of serious heart rhythm disturbances and fatal cardiac events.

Ventricular fibrillation (VF) is a disorganized and rapid rhythm of the cardiac ventricles that often leads to sudden cardiac death. Ventricular tachycardia (VT) is rapid and more organized rhythm that is also potentially fatal. Both VT and VF appear to be dependent on alterations in ventricular conduction and repolarization coupled with changes in the autonomic and vascular systems. The present invention uses high-resolution or low-resolution ECG data to identify novel ECG patterns closely linked to the subsequent development of serious heart rhythm disturbances and fatal cardiac events. 60 The patient data derived from the ECG waveforms results in high-dimensional data. Long ECG records exhibit complex nonlinear variability that cannot be efficiently captured by traditional modeling techniques.

Two approaches are disclosed to study the dynamical and 65 geometrical properties of ECG data. The first method uses a modified Matching Pursuit (MMP) algorithm to find a noise-

2

less model of the ECG data that is sparse and does not assume periodicity of the signal. After the model is derived, various metrics are extracted to localize different electrical abnormalities. In the second method, space-time domain is divided into 12 regions radially from the center of mass in 12 dimensional space; the dynamical density of the ECG signal is computed, using non-Fourier or Fourier n dimensional fractional integral summation across all ECG leads on the derived MMP model (Typically the order of fractional integral could be –1.5 or –2.5 or any irrational, complex or real number), in each region and input to a genetic learning algorithm to associate them with serious heart rhythm disturbances, sudden cardiac death, other modes of death, and all-cause mortality.

SUMMARY OF THE DISCLOSURE

The claimed invention generally relates to non-invasive methods and techniques for characterizing cardiovascular systems. More specifically, the claimed invention uses surface and other electrocardiographic (ECG) data to identify and localize novel ECG patterns that have been linked to the development of serious heart rhythm disturbances, sudden cardiac death, other modes of death, and all-cause mortality.

The present disclosure evaluates the electrical activity of the heart to identify novel ECG patterns closely linked to the subsequent development of serious heart rhythm disturbances and fatal cardiac events. The present invention provides an improved and efficient method to identify and risk stratify arrhythmias of the heart using ECG data. ECG waveforms are acquired and produce high-dimensional data that can be used to identify complex nonlinear variability that is not efficiently captured by traditional techniques. Two approaches, namely model-based analysis and space-time analysis, are used to study the dynamical and geometrical properties of the ECG data. In the first a model is derived using a modified Matching Pursuit (MMP) algorithm. Various metrics and subspaces are extracted to characterize the risk for serious heart rhythm disturbances, sudden cardiac death, other modes of death, and all-cause mortality linked to different electrical abnormalities of the heart. In the second method, space-time domain is divided into a number of regions (e.g., 12 regions), the density of the ECG signal is computed in each region and input to a learning algorithm to associate them with these events. Blinded validation of the utility of these algorithms was then carried out in an independent set of patients.

BRIEF DESCRIPTION OF THE DRAWINGS

Exemplary embodiments of the present disclosure will hereinafter be described in conjunction with the following drawing figures, wherein like numerals denote like elements, and wherein:

FIG. 1 shows the steps of the model-based analysis and Space-Time analysis to derive a noiseless model of the ECG data using a modified MP algorithm and linking the dynamical Space density metrics to Sudden Cardiac Death and All-Cause Mortality risk;

FIG. 2 shows the steps of the model-based analysis to derive a noiseless model from ECG data using a modified MP algorithm;

FIG. 3 presents process of phase space transformation;

FIG. 4 illustrates the process of selecting the best dictionaries;

FIG. **5** sketches model estimation process where sparse linear expansion of selected atoms is used to mimic the ECG signal;